



STATE BOARD OF EQUALIZATION

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Executive Director

October 31, 2008

Dear Interested Party:

Enclosed are the Agenda, Issue Paper, and Revenue Estimate for the November 12, 2008 Business Taxes Committee meeting. This meeting will address the proposed amendments to Regulation 1591, *Medicines and Medical Devices*, regarding ear implant devices.

If you are interested in other topics to be considered by the Business Taxes Committee, you may refer to the "Business Taxes Committee" page on the Board's Internet web site (<http://www.boe.ca.gov/meetings/btcommittee.htm>) for copies of Committee discussion or issue papers, minutes, a procedures manual, and a materials preparation and review schedule arranged according to subject matter and meeting date.

Thank you for your input on these issues. I look forward to seeing you at the Business Taxes Committee meeting at **9:30 a.m. on November 12, 2008**, in Room 121 at the address shown above.

Sincerely,

Randie L. Henry, Deputy Director
Sales and Use Tax Department

RLH:lrc

Enclosures

cc: (all with enclosures)

Honorable Judy Chu, Ph.D., Chair, Fourth District

Honorable Betty T. Yee, Vice Chairwoman, First District (MIC 71)

Honorable Bill Leonard, Member, Second District (MIC 78)

Honorable Michelle Steel, Member, Third District

Honorable John Chiang, State Controller, c/o Ms. Marcy Jo Mandel (via e-mail)

Mr. Steve Shea, Board Member's Office, Fourth District (via e-mail)
Mr. Mark Ibele, Board Member's Office, Fourth District (via e-mail)
Mr. Alan LoFaso, Board Member's Office, First District (via e-mail)
Ms. Sabina Crocette, Board Member's Office, First District (via e-mail)
Mr. Gary Qualset, Board Member's Office, First District (via e-mail)
Ms. Mengjun He, Board Member's Office, First District (via e-mail)
Ms. Amber Kemp, Board Member's Office, First District (via e-mail)
Mr. Lee Williams, Board Member's Office, Second District (via e-mail)
Mr. Ken Maddox, Board Member's Office, Third District (via e-mail)
Mr. Neil Shah, Board Member's Office, Third District (via e-mail)
Ms. Elizabeth Maeng, Board Member's Office, Third District (via e-mail)
Ms. Christina Rueck, Board Member's Office, Third District (via e-mail)
Ms. Melanie Darling, State Controller's Office (via e-mail)
Mr. Ramon J. Hirsig (via e-mail)
Ms. Kristine Cazadd (via e-mail)
Mr. Jeff Vest (via e-mail)
Mr. Robert Lambert (via e-mail)
Mr. Randy Ferris (via e-mail)
Mr. David Levine (via e-mail)
Mr. Timothy Treichelt (via e-mail)
Mr. Cary Huxsoll (via e-mail)
Mr. Robert Tucker (via e-mail)
Mr. Todd Gilman (via e-mail)
Ms. Laureen Simpson (via e-mail)
Mr. Robert Ingenito, Jr. (via e-mail)
Mr. Bill Benson (via e-mail)
Ms. Freda Orendt (via e-mail)
Mr. Stephen Rudd (via e-mail)
Mr. Kevin Hanks (via e-mail)
Mr. Jeff McGuire (via e-mail)
Mr. James Kuhl (via e-mail)
Mr. Geoffrey E. Lyle (via e-mail)
Ms. Leila Hellmuth (via e-mail)
Ms. Lynda Cardwell (via e-mail)
Ms. Cecilia Watkins (via e-mail)

AGENDA —November 12, 2008, Business Taxes Committee Meeting
Amend Regulation 1591, Medicines and Medical Devices

Action 1 — Regulation 1591	Approve and authorize publication of either:
Issue Paper Alternative 1	Staff's proposed amendments to Regulation 1591, subdivision (b)(2) to: <ul style="list-style-type: none">• Clarify that an ear implant includes the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted.
	OR
Issue Paper Alternative 2	Mr. Polley's proposed amendments to Regulation 1591, subdivision (b)(2) to: <ul style="list-style-type: none">• Clarify that <i>all</i> "permanently implanted articles" include the implant's interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of "medicines."

AGENDA —November 12, 2008, Business Taxes Committee Meeting
Amend Regulation 1591, Medicines and Medical Devices

Action Item	Regulatory Language Proposed by Staff	Regulatory Language Proposed by Polley
Action 1 – Regulation 1591, Subdivision (b)(2)	<p>(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, <u>including the ear implant's interdependent internal and external components that operate together as one device in</u></p>	<p>(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. <u>Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted.</u> Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, <u>including the ear implant's interdependent internal and external components.</u></p>

AGENDA —November 12, 2008, Business Taxes Committee Meeting
Amend Regulation 1591, Medicines and Medical Devices

Action Item	Regulatory Language Proposed by Staff	Regulatory Language Proposed by Polley
	<p><u>and on the person in whom the device is implanted.</u> Sutures are also included whether or not they are permanently implanted. non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.</p> <p>Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.</p>	<p>Sutures are also included whether or not they are permanently implanted. non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.</p> <p>Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.</p>

Issue Paper Number **08-012**



- ☐ Board Meeting
- ☒ Business Taxes Committee
- ☐ Customer Services and Administrative Efficiency Committee
- ☐ Legislative Committee
- ☐ Property Tax Committee
- ☐ Other

Proposed Amendments to Regulation 1591, *Medicines and Medical Devices*, Regarding Ear Implant Devices

I. Issue

Should Regulation 1591, *Medicines and Medical Devices*, be amended to clarify the application of tax to sales of ear implant devices with their mutually dependent internal and external components?

II. Alternative 1 – Staff Recommendation

Staff recommends amending Regulation 1591, subdivision (b)(2), to clarify that an ear implant includes the interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted, to assist in the ongoing functioning of the ear. When the sale of the ear implant qualifies for exemption from tax, the exemption extends to the sale of the interdependent external components.

Staff's proposed amendments are reflected in Exhibit 2.

III. Alternative 2 – Other Alternative Considered

As proposed by Mr. Terry L. Polley of the firm Ajalat, Polley, Ayoob & Matarese, amend Regulation 1591, subdivision (b)(2), to include in the definition of "permanently implanted articles" the interdependent internal and external components of an implanted article, which operate together as one device, in and on the person in whom the device is implanted. Unlike staff's proposed amendment, which is limited to clarification regarding ear implants, this amendment would clarify the application of tax to *all* permanently implanted articles and the implanted article's interdependent external components.

Mr. Polley's proposed amendments are reflected in Exhibit 3.

IV. Background

Revenue and Taxation Code (RTC) section 6369, interpreted and implemented by Regulation 1591, provides that sales of medicines furnished for the treatment of a human being are exempt from sales or use tax if they are sold or furnished under certain conditions, as described in subdivisions (a)(1) through (a)(6) of that section. The term “medicines” is defined by RTC section 6369, subdivision (c), in part, to mean and include “bone screws, bone pins, pacemakers, and other articles, other than dentures, permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body.”

Regulation 1591, subdivision (b)(2), provides in part and with emphasis added:

“Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines....”

“Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and **ear implants**.”

On February 27, 2008, the Board of Equalization (Board) heard a sales and use tax appeals case regarding the sales of cochlear implant devices. At issue was whether sales of the external components of the ear implant device qualified for exemption from tax in the same manner as the permanently implanted internal components. The petitioner explained that the internal and external components of the ear implant device are effectively one device, with each component mutually dependent on the other to function. Together, the internal and external components of the ear implant device assist in the functioning of the ear, each necessary and integral to the ongoing function of the ear and, as such, both qualify as “medicines.” The Board agreed with the petitioner and instructed staff to amend Regulation 1591 to clarify the matter.

Staff and interested parties met on July 16, 2008, to discuss staff’s proposed language to amend Regulation 1591. Based on discussions at the meeting, staff modified its proposed regulatory amendments for clarity and to remove any examples of qualifying components since the nature of the components could vary depending on the type of ear implant device.

Staff and interested parties also met on September 9, 2008, to discuss the changes made to staff’s initial revisions to Regulation 1591 suggested during the first interested parties meeting and a proposal from Mr. Polley to expand the proposed amendments to subdivision (b)(2) to apply to *all* permanently implanted articles, not just ear implants. Staff considered the suggested expansion; however, since it is believed outside the scope of the direction from the Board, staff’s proposed amendments remain specific to ear implants. Staff’s proposed amendments are reflected in Exhibit 2. Mr. Polley’s proposed amendments are reflected in Exhibit 3.

The Business Taxes Committee is scheduled to discuss the proposed amendments at its meeting on November 12, 2008.

V. Discussion

As provided by Regulation 1591, permanently implanted articles, the sales of which qualify for exemption from tax when certain conditions are met, include articles that are implanted in the human body to assist in the functioning of any natural organ (e.g., heart), artery (e.g., blood vessels that carry blood away from the heart), vein (e.g., blood vessels that carry blood to the heart) or limb and which remain or dissolve in the body. It appears that most qualifying articles, which are intended to function in this manner, are fully implanted in the body; however, this is not currently the case with an ear implant, as discussed below.

Ear implants – In general, an ear implant is a permanently implanted device, which is surgically implanted into the ear (i.e., inner, middle, or outer ear) or surrounding area to assist in, rather than replace, the functioning of the ear. The ear implant generally consists of internal and external components that effectively function together as one unit with each component mutually dependent on the other to function. Notable for all of the interdependent components is the fact that they function together “in or on” the person in whom the device is implanted.

There are different types of ear implants currently available for surgical implanting. The implant and the technology used differ depending on the damage to the ear or nature of the hearing loss. For example, an ear implant may use electrodes implanted in the inner ear (cochlea) to stimulate the auditory nerve with electrical signals the brain can interpret as sound *or* it may penetrate into the auditory portion of the brainstem to produce localized stimulation of the cochlear nucleus and send sound signals to the brain. Unlike hearing aids, these implants do not amplify sound, but work by directly stimulating any functioning auditory nerves inside the cochlea with the electric field stimulated through an electric impulse.

Ear implants generally consist of an external component that includes a microphone and speech/audio processor and an implanted component that generally includes the electronic housing and the attached electrodes. The interdependent external components of the ear implant generally include items such as a coil and magnet, with its protective cover, coil plug, connecting pins and cable; a speech/audio processor with the required connecting pins, microphone, and internal electronics; a battery pack/control unit, with the necessary batteries, connecting pins, and cables; and a headpiece or ear hook. Combined, the external components can consist of numerous parts that may require replacement.

There are also numerous accessories available for persons with an ear implant that are not an interdependent component of the implant. For example, items such as an auxiliary microphone for use with hearing-compatible telephones or for use in loud environments, microphone or processor test devices, system sensor/diagnostic tools, microphone testers, battery or power cell charging systems and car adapters, travel cases, sport carrying cases, key cases that also hold a spare power cell, and tote bags are available for persons with a cochlear implant. There are also similar accessories available for the other types of ear implants.

Replacement components – For the purposes of Regulation 1591, subdivision (b)(2), the exemption for the sale of an ear implant and its interdependent components would also apply to the sale of replacement components or upgrades to such components when they replace or upgrade the interdependent components originally provided as part of the ear implant. For example, if a speech/audio processor originally provided to a patient as a component of his or her cochlear implant were damaged, the sale of a replacement processor or one of its functional internal components would qualify for exemption from tax in the same manner as the original component. Replacement of the processor or its internal component would be necessary for the ongoing functioning of the ear implant.

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Accessories for the implant – As noted previously, there are various accessories available to a person with an ear implant. Unlike the replacement of an interdependent component of an ear implant, however, the sale of these items would not qualify as the sale of an exempt “medicine.” Although the accessories may be provided or sold to the patient separately or for a single price with the implant, the accessories are not an interdependent component of the implant, nor do they assist in the ongoing functioning of the ear. Since the implanted device can function effectively without these items, they would be excluded from the definition of “medicines.” This would also be true for the programming software used to create, adjust, fine tune, or optimize the sound/speech processing programs.

Interested party submission – Prior to the second interested parties meeting held on September 9, 2008, staff received a submission proposing that staff’s amendment to Regulation 1591, subdivision (b)(2), be expanded to apply to all permanently implanted articles, not just ear implants. As explained by Mr. Polley in his August 26, 2008 submission, “an auditor may draw the negative implication that interdependent external parts of other implants do not qualify [as medicines].” Mr. Polley believes such an expansion will prevent other taxpayers from having to take cases similar to the cochlear implant case to the Board in the future.

VI. Alternative 1 - Staff Recommendation

A. Description of Alternative 1

Staff recommends that Regulation 1591 be amended to clarify that tax does not apply to sales of the interdependent internal and external components of an *ear implant* that operate together as one device in and on the person in whom the device is implanted. Such components function together with the implant as one unit, which together assist in the functioning of the ear.

As noted under Alternative 2, both staff and Mr. Polley propose to amend Regulation 1591, subdivisions (b)(2) to clarify the application of tax to sales of the interdependent internal and external components of a permanently implanted article. However, staff’s proposed amendment to subdivision (b)(2) is limited to clarification regarding sales of ear implants, whereas Mr. Polley’s proposed amendment clarifies the application of tax to all permanently implanted articles, including ear implants. In essence, Mr. Polley’s proposed amendment extends the Board’s decision in the February 27, 2008 appeals hearing to any permanently implanted article, except when the interdependent components are otherwise excluded from the definition of “medicines.”

Proposed amendments

In holding with the direction of the Board, staff recommends that, in addition to the two minor punctuation edits shown in bold text with strikeout and underline (edits agreed to by Mr. Polley), the second paragraph of subdivision (b)(2) be amended as follows:

(2) **PERMANENTLY IMPLANTED ARTICLES.**Permanently implanted articles include, but are not limited to; ~~permanently implanted artificial sphincters; bone screws and bone pins;~~ ... and ear implants, including the ear implant’s interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted.

Staff’s proposed amendments to Regulation 1591 are reflected in Exhibit 2.

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B. Pros of Alternative 1

- The proposed amendments clarify that the internal and external components of an ear implant, which are mutually dependent on the other to function, are effectively one device.
- The proposed amendments are specific to ear implants, which staff believes is consistent with the direction of the Board.
- The proposed amendments clarify that when the interdependent external components of an ear implant are worn “on” the person in whom the device is implanted such components are included in the definition of a permanently implanted article in the same manner as the ear implant.

C. Cons of Alternative 1

- The proposed amendments do not clarify whether the interdependent components of other implanted articles qualify as “medicines.”
- Since the proposed amendments are limited to ear implants, this may be perceived by some as an inconsistent application of the law.

D. Statutory or Regulatory Change for Alternative 1

No statutory change is required. However, staff’s recommendation does require the amendment of Regulation 1591.

E. Operational Impact of Alternative 1

Staff will notify taxpayers of the amendments to Regulation 1591 through the Tax Information Bulletin (TIB).

F. Administrative Impact of Alternative 1

1. Cost Impact

The workload associated with publishing the regulation and TIB is routine. Any corresponding cost would be absorbed within the Board’s existing budget.

2. Revenue Impact

None. See Revenue Estimate (Exhibit 1)

G. Taxpayer/Customer Impact of Alternative 1

Overall taxpayer impact is minimal since the proposed amendments clarify rather than change the current application of tax.

H. Critical Time Frames of Alternative 1

Implementation will take place 30 days following approval of the regulation by the State Office of Administrative Law.

VII. Alternative 2 – Mr. Polley’s Proposal

A. Description of Alternative 2

Like staff, Mr. Polley recommends that Regulation 1591 be amended to clarify that tax does not apply to the sale of the interdependent internal and external components of an ear implant that operate together as one device in and on the person in whom the device is implanted. However, consistent with what he believes to be the intent of the Board, Mr. Polley proposes that Regulation 1591, subdivision (b)(2), be amended to clarify the application of tax to sales of the interdependent internal and external components of *any* implanted article, which operate together as one device to assist in the functioning of any natural organ, artery, vein, or limb, except for devices excluded from the definition of “medicines.” Mr. Polley believes the amendment to subdivision (b)(2) is necessary for consistency and clarity.

Whereas staff’s proposal limits the amendment to Regulation 1591 to clarification regarding the application of tax to sales of the interdependent internal and external components of an ear implant, Mr. Polley’s proposal would effectively extend the principle related to ear implants to other similarly situated articles and provide clarification regarding this principle in the regulation. Devices that are excluded from the definition of “medicines” by statute, would not qualify even though the device may consist of interdependent components, which effectively function together as one device.

As stated previously, staff does not believe the Board intended for Regulation 1591 to be amended to clarify the application of tax to sales of other similarly situated implanted articles when they instructed staff to amend Regulation 1591.

Proposed amendments

Mr. Polley proposes that the first paragraph of subdivision (b)(2) be amended to provide that:

“(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted....”

Like staff, Mr. Polley also recommends that the second paragraph of subdivision (b)(2) be amended to clarify the application of tax to ear implants specifically; however, since the principle behind the Board’s decision in the appeals case is reflected in the proposed amendment to the first paragraph, the paragraph should be amended as follows:

...Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins; ... and ear implants, including the ear implant’s interdependent internal and external components.

Mr. Polley’s proposed amendments to Regulation 1591 are reflected in Exhibit 3.

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B. Pros of Alternative 2

- The proposed amendments clarify that the internal and external components of an implant, which are mutually dependent on the other to function, are effectively one device.
- The proposed amendments clarify the application of tax to sales of *all* implanted articles, which may be perceived as a more consistent application of the law.

C. Cons of Alternative 2

- The proposed amendments appear broader than intended by the Board.

D. Statutory or Regulatory Change for Alternative 2

No statutory change is required. However, proposal does require the amendment of Regulation 1591.

E. Operational Impact of Alternative 2

Staff will notify taxpayers of the amendments to Regulation 1591 through the Tax Information Bulletin (TIB).

F. Administrative Impact of Alternative 2

1. Cost Impact

The workload associated with publishing the regulation and TIB is routine. Any corresponding cost would be absorbed within the Board's existing budget.

2. Revenue Impact

None – See Revenue Estimate (Exhibit 1)

G. Taxpayer/Customer Impact of Alternative 2

Overall taxpayer impact would be minimal.

H. Critical Time Frames of Alternative 2

Implementation will take place 30 days following approval of the regulation by the State Office of Administrative Law.

Preparer/Reviewer Information

Prepared by: Tax Policy Division

Current as of: 10/30/2008

REVENUE ESTIMATESTATE OF CALIFORNIA
BOARD OF EQUALIZATION

**Proposed Amendments to Regulation 1591, *Medicines and Medical Devices*,
Regarding Ear Implant Devices****Alternative 1 – Staff Recommendation**

Staff recommends amending Regulation 1591, subdivision (b)(2), to clarify that an ear implant includes the interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted, to assist in the ongoing functioning of the ear. When the sale of the ear implant qualifies for exemption from tax, the exemption extends to the sale of the interdependent external components.

Alternative 2 - Other Alternative Considered

As proposed by Mr. Terry L. Polley of the firm Ajalat, Polley, Ayoob & Matarese, amend Regulation 1591, subdivision (b)(2), to include in the definition of “permanently implanted articles” the interdependent internal and external components of an implanted article, which operate together as one device, in and on the person in whom the device is implanted. Unlike staff’s proposed amendment, which is limited to clarification regarding ear implants, this amendment would clarify the application of tax to *all* permanently implanted articles and the implanted article’s interdependent external components.”

Background, Methodology, and Assumptions**Alternative 1 – Staff Recommendation**

There is nothing in staff recommendation that would impact sales and use tax revenue. Staff recommendation clarifies that tax does not apply to the sale of the interdependent internal and external components of an ear implant that operate together as one device in and on the person in whom the device is implanted. Such components function together with the implant as one unit, which together assist in the functioning of the ear.

Also, staff recommendation clarifies the application of tax to sales of the interdependent internal and external components of a permanently implanted device. However, staff’s proposed

amendment is limited to ear implants, whereas the other alternative's proposed amendment is intended to apply to all permanently implanted articles, including ear implants.

Alternative 2 - Other Alternative Considered

There is nothing in the alternative 2 that would impact sales and use tax revenue. Similar to staff recommendation, alternative 2 would clarify that tax does not apply to the sale of the interdependent internal and external components of an ear implant that operate together as one device in and on the person in whom the device is implanted. However, proponents of alternative 2 believe that, for consistency and clarity, Regulation 1591 (b) (2) should be amended to clarify the application of tax to sales of the interdependent internal and external components of *any* implanted article, which operate together as one device to assist in the functioning of any natural organ, artery, vein, or limb.

Revenue Summary

Alternative 1 – staff recommendation does not have a revenue impact.

Alternative 2 – alternative 2 does not have a revenue impact.

Preparation

Mr. Bill Benson, Jr., Research and Statistics Section, Legislative and Research Division, prepared this revenue estimate. Mr. Robert Ingenito, Jr., Manager, Research and Statistics Section, Legislative and Research Division, and Mr. Jeff McGuire, Tax Policy Manager, Sales and Use Tax Department, reviewed this revenue estimate. For additional information, please contact Mr. Benson at (916) 445-0840.

Current as of October 30, 2008.

Regulation 1591. MEDICINES AND MEDICAL DEVICES.

Reference: Sections 6006 and 6369 Revenue and Taxation Code, and sections 1200, 1200.1, 1204.1, and 1250 Health and Safety Code.

(a) DEFINITIONS.

(1) ADMINISTER. “Administer” means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. “Dispense” means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. “Furnish” means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. “Health Facility” as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, and also includes “clinic” as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that “health facility” means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that “clinic” means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that “clinic” also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient’s ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) PHARMACIST. “Pharmacist” means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.

(6) PHARMACY. “Pharmacy” means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances,

dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) **PRESCRIPTION.** “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) **PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS.** “Physicians,” “dentists,” “optometrists,” and “podiatrists” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) **MEDICINES.** “Medicines” means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) **“MEDICINES.”** In addition to the definition set forth in subdivision (a)(9) of this section, the term “medicines” means and includes the following items:

(1) **PREPARATIONS AND SIMILAR SUBSTANCES.** Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

“Preparations and similar substances” include, but are not limited to, drugs such as penicillin, and other antibiotics, “dangerous drugs” (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. “Preparations and similar substances” also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503.

For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant’s interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) ARTIFICIAL LIMBS AND EYES. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. “Custom-made biomechanical foot orthosis” means a device that is made on a positive model of the individual patient’s foot. The model may be

individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient’s foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient’s shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacement parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as “medicines,” include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; ~~and~~ vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF “MEDICINES.” Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX—IN GENERAL. Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

(1) **PRESCRIPTIONS.** No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) **LICENSED PHYSICIAN, DENTIST OR PODIATRIST.** Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge-to his or her patient for the medicines furnished.

(3) **HEALTH FACILITY.** Tax does not apply to sales of medicines by a health facility (as defined in subdivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the “sample” medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the “samples” whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration’s drug development and approval process. “Clinical trial medicines” are substances or preparations approved as “Investigational New Drugs” by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. “Clinical trial medicines” do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient’s treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (“in vitro”) in an artificial environment. They are not administered in the living body (“in vivo”). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) INSURANCE PAYMENTS

(1) MEDICAL INSURANCE AND MEDI-CAL. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) MEDICARE

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) EMPLOYER MEDICAL CONTRACTS. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are “deemed to be dispensed on prescription” within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) “DOUBLE DEDUCTION” UNAUTHORIZED. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

Regulation 1591. MEDICINES AND MEDICAL DEVICES.

Reference: Sections 6006 and 6369 Revenue and Taxation Code, and sections 1200, 1200.1, 1204.1, and 1250 Health and Safety Code.

(a) DEFINITIONS.

(1) ADMINISTER. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. "Furnish" means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. "Health Facility" as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) PHARMACIST. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.

(6) PHARMACY. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances,

dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) **PRESCRIPTION.** “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) **PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS.** “Physicians,” “dentists,” “optometrists,” and “podiatrists” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) **MEDICINES.** “Medicines” means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) **“MEDICINES.”** In addition to the definition set forth in subdivision (a)(9) of this section, the term “medicines” means and includes the following items:

(1) **PREPARATIONS AND SIMILAR SUBSTANCES.** Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

“Preparations and similar substances” include, but are not limited to, drugs such as penicillin, and other antibiotics, “dangerous drugs” (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. “Preparations and similar substances” also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503.

For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to: permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant’s interdependent internal and external components.—Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) ARTIFICIAL LIMBS AND EYES. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacement parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; ~~and~~ vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES." Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX—IN GENERAL. Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

(1) **PRESCRIPTIONS.** No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) **LICENSED PHYSICIAN, DENTIST OR PODIATRIST.** Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge-to his or her patient for the medicines furnished.

(3) HEALTH FACILITY. Tax does not apply to sales of medicines by a health facility (as defined in subdivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the “sample” medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the “samples” whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration’s drug development and approval process. “Clinical trial medicines” are substances or preparations approved as “Investigational New Drugs” by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. “Clinical trial medicines” do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient’s treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (“in vitro”) in an artificial environment. They are not administered in the living body (“in vivo”). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) INSURANCE PAYMENTS

(1) MEDICAL INSURANCE AND MEDI-CAL. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) MEDICARE

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) EMPLOYER MEDICAL CONTRACTS. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are “deemed to be dispensed on prescription” within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) “DOUBLE DEDUCTION” UNAUTHORIZED. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.